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Subject Letter of Promulgation

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Section 2

Letter of Promulgation

We recognize that the quality of experimental data has a direct impact on the quality of our research. By using the tools described in this plan, researchers will be able to meet the Center quality measurement goals. Meeting those goals will permit the Center to generate experimental data upon which technical decisions can be made with a high confidence.

This plan has the support of the Biotechnology Center for Fuels and Chemicals, and I expect all Center researchers to adhere to the guidelines set in this plan, so that data generated will meet or exceed customer expectations.

Charles E. Wyman



Section 3

Background

3.1 Purpose

As part of the National Renewable Energy Laboratory (NREL), the Biotechnology Center for Fuels and Chemicals (Center) conducts research for the U.S. Department of Energy (DOE).

3.2 Scope

This section describes the Center mission, quality assurance (QA), and quality control (QC).

3.3 Center Mission/Vision

The Center's goal is to discover and develop cost-effective biotechnologies to convert biomass to renewable chemicals and to ethanol for use as a transportation fuel. The Center mission/vision statement is: "Biotechnology for fuels and chemicals to improve people's lives."

3.4 Definition of Quality Assurance

QA is a management system that assures analytical data producers and users that sound QC practices are being applied and that the data meet their requirements. It encompasses all aspects of the analytical process, including:

- Quality control
- Making measurements
- Recordkeeping
- Analyst training
- Managing data
- Client communication.¹

3.5 Definition of Quality Control

QC is the routine application of procedures for attaining prescribed performance standards in the measuring process. Examples of QC activities are:

- Calibrating an instrument to required specifications
- Correlating with other tests, certified reference standards, or other laboratories to confirm accuracy
- Running replicate analyses to establish precision
- Analyzing calibration and method verification standards to check performance

¹ Amoco Corporation. (1986). *Users Guide to Quality Assurance*. Naperville, Illinois.

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- Analyzing blanks to check for outside interferences
- Using control charts of QC data to monitor test behavior.¹

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Section 4

Introduction

4.1 Purpose

Appropriate quality experimental data are vital to understanding the biomass-to-chemicals process and to guide decisionmaking. By meeting the quality measurement goals, the Center will facilitate more efficient progress toward its goals.

4.2 Scope

This manual contains the Center Experimental Data Quality Assurance Plan, which is designed to ensure that all experimental data meet Center needs. The plan describes the core concepts and tools used to accomplish the Center's quality measurement goals.

4.3 Center Experimental Measurement Goals

By adopting the techniques outlined in this plan, the Center will meet the following experimental measurement goals:

- Generate comparable data from all sources
- Generate accurate and precise data that meet experimental plan needs
- Document that data meet required standards
- Enhance communication of measurement and variability issues
- Develop or enhance useful analytical methods
- Become a benchmark for biomass research
- Provide a management document against which the Center can be evaluated.

4.4 Appropriate levels of quality

Developing quality experimental data is always a balance between time and level of quality (data accuracy, precision, and ruggedness). To determine the appropriate level of quality, the costs associated with each choice must be understood. More time and effort are required to produce highly accurate, precise, and rugged data. This extra time and effort may be wasted if the level of quality greatly exceeds requirements. Conversely, time is not saved if experiments are inconclusive or poor decisions result from poor data. The level of quality must be matched to the experimental plan needs.

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4.5 Quality Measurement Tools

Supporting the plan are four important tools that can be tailored to meet the Center's measurement needs.

Experimental plans guide the research by stating the hypothesis, resources needed, tactics employed, and the data quality objectives (DQOs). The DQOs set the accuracy, precision, and ruggedness criteria for an experimental plan. These are described in Section 6, Quality Experimental Plans.

Sampling and Analysis Plans (SAPs) communicate to researchers the sample size, frequency, and preservation needed ensure the conclusions drawn from the experimental data can be related to the bulk sample. SAPs are described further in Section 7, Sampling and Sample Handling.

Laboratory Analytical Procedures (LAPs) are validated, documented procedures of general interest to the ethanol project. All analytical methods used in the ethanol project must be documented to meet requirements set in the DQOs and must be strictly followed to ensure quality results. These procedures are described in Section 8, Laboratory Analytical Procedures.

Subcontract research for the ethanol project shall be governed by a statement of work (SOW), a contractual document that identifies the research goals, sampling issues, and procedures used, and references this plan. Responsibilities associated with completing the terms of an SOW are described in Section 14, Quality Assurance for Subcontractors.



Section 5

Quality Assurance Responsibilities

5.1 Purpose

Every Center staff member has a role in attaining the quality measurement goals. The specific role each person plays must be clearly defined.

5.2 Scope

The QA responsibilities associated with various job functions are described below.

5.3 Center Staff Members Responsibilities

The Biotechnology Center is divided into teams, which coordinate their activities through the steering team and are responsible to the center director. Teams carry out the missions of the center. They are responsible to:

- Set directions and objectives for their research
- Coordinate their plans with the steering team
- Allocate team resources to meet team objectives
- Identify experimental designers to develop experimental plans.

Experimental designers are named by their team to draw up an experimental plan that helps meet the team's objectives. They conceive, plan, coordinate, and draw conclusions from experiments. They are responsible to:

- Develop experimental plans that meet team objectives
- Determine appropriate level of accuracy, precision, and ruggedness needed to meet experimental objectives
- Communicate experimental requirements to all involved researchers
- Choose analytical methods that meet experimental plan needs
- Implement quality tools into all research activities
- Defend conclusions drawn from their experimental plan.

Additional researchers may be assigned by the team to help the experimental designer execute the plan. They are responsible to:

- Generate data that meet experimental plan requirements
- Implement quality tools into all research activities
- Document QA/QC activities such as control charts and maintenance logs
- Maintain laboratory equipment
- If needed, develop, document, and validate new analytical methods.

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The quality control coordinator is responsible to:

- Ensure QA is being implemented
- Enable Center staff members to implement quality tools in their research
- Seek out and evaluate new ideas in the QC field
- Develop, distribute, and revise this plan
- Distribute and maintain laboratory analytical procedures
- Distribute and track conformance evaluation standards (CES).

5.4 Responsibilities Regarding Subcontracts

Research monitors (RMs) are Center staff who are responsible to:

- Draft the original statement of work (SOW)
- Ensure the SOW includes references this plan
- Determine appropriate level of accuracy, precision, and ruggedness needed to meet experimental objectives
- Monitor progress of subcontract
- Be a technical resource to subcontract staff
- Approve subcontractor CES results
- Coordinate activities between NREL staff and principal investigators (PIs)
- Ensure subcontractor activities support the SOW
- Track subcontract deliverables.

Subcontractor PIs lead outside research groups. They are responsible to:

- Ensure the quality of research
- Complete the terms of the SOW
- Allow only qualified people to conduct research
- Implement quality tools into research
- Document that the research meets experimental plan needs.



Section 6

Quality Experimental Plans

6.1 Purpose

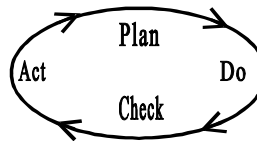
Quality data does not happen by chance, but must be designed into an experimental plan from the beginning. The experimental plan guides researchers to cost-effectively generate appropriate quality data in the minimum amount of time.

6.2 Scope

The rationale behind and requirements for experimental plans are described in this section.

6.3 Approach to Experimental Planning

The act of planning is envisioning an objective, gathering the available resources, and communicating to a team the means for achieving it. Planning is best accomplished by communicating with all stakeholders and is, whenever possible, a result of team consensus. Quality experimental planning is often represented by a quality circle:



Too often the planning step is short-changed in the interest of moving ahead. If the planning process is inadequate, the toll may be paid later in the form of below adequate quality data, repeated, or inconclusive experiments. Planning is an iterative process; it builds on previous results. By checking the plan throughout the experiment, adjustments can be made to ensure appropriate quality data are gathered.

6.4 Quality Experimental Plans

The experimental plan is written by an experimental designer. It describes the objectives for the experiment and the hypothesis being tested. The plan objectives help focus the designer, and any researchers assigned to help, on the requirements for resources needed, timeframe involved, responsibilities to be assigned, sampling and analysis plan (SAP), and data quality objectives (DQOs). The DQOs are analytical requirements for precision and detection limits.

The experimental plan shall be written and understood by all prior to commencing the experiment. All data generated must meet the plan DQOs. Throughout the experimental lifetime, the DQOs may be changed to reflect changing needs. These updated DQOs must be communicated to all team members.

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Section 7

Sampling and Sample Handling

7.1 Purpose

Typically, an analysis is performed on a sample taken from a larger population. Anything that causes the sample to differ from the whole population will confound the conclusions drawn from the data analysis. Because no analysis can be better than the original sample, all aspects of sampling and sample handling must incorporate sound quality principles.

7.2 Scope

This section describes sampling variables that must be controlled to help ensure the sample analytical results reflect the entire population.

7.3 Sampling and Analysis Plan

The experimental designer develops, as part of the experimental plan, a sampling and analysis plan (SAP). The SAP sets the requirements for the sampling process and precautions to ensure sampling quality. The SAP identifies the analytes of interest, the analytical procedure (LAP or other method) to be used, the sampling frequency, and required sample quantities.

7.4 Sampling Issues

All efforts shall be made to ensure that an aliquot representative of the entire population is obtained at every sampling step. Samples shall be representatively drawn, well mixed, and large enough to adequately model the population.

All efforts shall be made to ensure adequate sample amounts are submitted for analysis. Abundant sample quantities enable the analyst to run samples in replicate, and, if necessary, make reruns. Insufficient sample amounts compromise the stated precision limits developed for a particular method.

7.5 Sample Preservation

Unprotected samples can change, and the results of their analysis can lead to erroneous conclusions. All samples shall be stored in a manner that preserves their integrity. Samples must be protected from precipitation, volatilization, degradation, microbiological contamination, and other corruption. Time limits may need to be set to ensure that the analysis is complete before the sample begins to change.

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7.6 Sample Receiving and Reporting

Samples turned over for analysis must be accompanied by a written document describing the samples and the tests to be performed. This helps ensure that each sample group is properly identified and is analyzed and reported in a timely manner. Small groups of like samples can be tracked, analyzed, and reported together. Large, ongoing experiments may require a separate tracking log to document samples submitted and results generated.

7.7 Sample Disposal

On completion of the analysis, samples shall be returned to the requestor, who shall be responsible for proper disposal.

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Section 8

Method Development and Validation

8.1 Purpose

Changes are constantly occurring to the types of samples generated and analytical questions asked about them. Analytical methods may need to be improved or new methods developed in order to properly analyze these samples.

8.2 Scope

This section discusses development and validation issues that must be addressed to produce useful analytical methods.

8.3 Method Types

There are many types of methods, and each has strengths and weaknesses. Investigative methods are "quick-and-dirty" methods used to confirm the presence of compounds. Screening or tracking methods are useful to check for changes in a process, but not for highly accurate quantitation. Laboratory analytical procedure (LAP) methods produce data suitable for mass closure calculations, publications, and comparisons to other analytical methods. The researcher or experimental designer must understand a method's strengths and weaknesses, and choose the most appropriate method to meet the experimental plan DQOs.

8.4 New Method Development Considerations

New method development takes many steps and must be done methodically in order to produce a useful procedure. A thorough understanding of the purpose, precision, and repeatability is necessary to guide method development. Identifying the analytes of interest and expected analyte levels, and identifying any potential interferences are the next steps. Sample preparation steps, such as cleanup and concentration, need to be identified and incorporated into the procedure. Appropriate analytical standards need to be developed and tested.

8.5 Method Enhancement Considerations

A validated method cannot be assumed to generate quality data if the samples, analytes, or matrices are different from the original method development. Methods must be validated for new substrates or analytes outside the original method scope. Methods may need to be developed or enhanced when the objectives for a particular analysis change. Subtle changes to a method scope such as changes to QA/QC limits, various sampling schemes, or changes to the experimental process may also require method development or enhancement.

Method enhancement starts with a validated method and extends the scope. This can be much easier and less time consuming than new method development, but must be performed critically in

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order to ensure the enhanced method is useful. The enhanced method needs to be tested to ensure that the QC limits have not changed and that no new interferences affect the results. The enhanced method must again be validated before use.

8.6 Method Validation

Method validation is the act of documenting the capabilities of a method. Real samples or a well-matched standard reference material needs to be run in parallel with validated methods. If the data comparison is acceptable, the method must be written up in detail. Multiple replicates must be run to determine the method variability and run-to-run reproducibility. Permissible QC limits for blanks analysis, calibration verification standards, method verification standards, and replicates need to be incorporated into the writeup. A method must be validated by those who develop it.

8.7 Method Development or Enhancement responsibilities

Any researcher can develop or enhance analytical methods. Any method used must be written and demonstrated to meet the DQO requirements of the experimental plan. Center analytical chemists are available to develop methods or to advise researchers concerning method development.

Subject Laboratory Analytical Procedures

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Section 9

Laboratory Analytical Procedures

9.1 Purpose

The results generated from the analyses used in the Center are often highly dependent on the procedure used. Small variations from a validated procedure can greatly affect the final result. Therefore, the precise analytical protocols must be specified and followed.

9.2 Scope

This section describes laboratory analytical procedures (LAPs), which are validated, documented, and management approved analytical test procedures, capable of producing publication-quality data.

9.3 Criteria for LAPs

LAPs have been validated as described in Section 8, Method Development and Validation. LAPs shall be written according to the LAP style guide. A LAP contains background information, references, equipment required, calculations, and QC limits. They describe the analytical procedure in sufficient detail that a researcher can repeat the process using no other source.

9.4 LAP Quality Control

Each LAP shall describe QC activities that must be followed to ensure the precision limits are being met. All data generated using a LAP must meet the QC specifications stated in the procedure. These QC activities may include the analysis of a blank, method verification standard (MVS), and calibration verification standard (CVS).

Analysis of a blank is used to demonstrate that the environment, reagents, or equipment are not inducing a response that could be interpreted as having come from the sample. A blank is an analysis run using the same equipment, reagents, and procedure, but without the sample.

MVSs are used to demonstrate that a method is stable and reproducible. They give the researcher confidence that any changes observed in the results are caused by experimental conditions rather than analytical variability. There are two types of MVS: well-characterized materials and spikes. Well-characterized materials are of known composition and similar to the type samples usually analyzed by a method. In situations where stable, well-characterized materials are not available, spiking samples with representative analytes of interest are used as a MVSs.

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The analytical variability is not the same as experimental error. Errors in sampling, sample handling, and analytical variability contribute to the overall experimental error. Knowing the experimental error is a crucial part of any experimental plan. This may be estimated by running replicate conditions, control samples, or a well-matched MVS material.

CVSs are standards used to check the stability of an instrument's calibration. They ensure that the response of an analytical instrument has not changed since it was last calibrated. A CVS shall be prepared from a different lot (and preferably a different manufacturer) than the analytical standards used to calibrate an instrument. A CVS shall be prepared at a concentration between, but not equal to, the concentrations of the analytical standards. CVSs shall be run periodically throughout an instrumental run.

9.5 LAP Distribution to Center Researchers

The LAPs are available to Center staff members in a "read-only" directory on the Local Area Network (LAN). LAPs are located in the U:\NGROUP\ETHANOL directory of the 16/3 file server. It may be necessary to attach to this server in order to access the files. Only the most current, approved revision of each LAP shall be available on the LAN. When changes are made to the LAPs on the LAN, a memo shall be distributed to alert the users. Center staff shall be responsible for ensuring they are using the most current LAP version.

9.6 Identifying New LAPs

Developed and validated methods may become LAPs if they are of general interest to the Center. New, validated methods may be included in the Center LAP manual.

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Section 10

Quality Control of Measuring Equipment

10.1 Purpose

All measuring equipment will introduce uncertainty into an analysis. No apparatus should be overlooked as a potential error source. Sound QC checking and maintenance practices must be applied to all measuring equipment to minimize error and downtime.

10.2 Scope

This section describes good QC and maintenance practices for laboratory equipment.

10.3 General Considerations

Experimental planners and researchers must consider the implications of uncertainties caused by measuring equipment. Within an experimental plan, certain measurements are critical to the final result. QC practices for such critical equipment must be more rigorous than for other equipment. QC checks, maintenance plans, and QC documentation for critical equipment shall be developed to ensure they produce acceptable-quality data.

10.4 Simple Measuring Equipment

Many types of simple measuring equipment can be overlooked as error sources. Data gathered using pH probes, pressure sensors, autopipettes, thermometers, flow sensors, or other types of equipment may cause large errors in an experimental plan. If such equipment is critical to the plan, a formal program needs to be developed to regularly check and document its calibration.

10.5 Advanced Instrumentation

Advanced instrumentation, such as HPLC or GCs, require continuing QC checks and maintenance records to minimize data uncertainty. Current maintenance records shall be located near an instrument to document proper maintenance. Maintenance records shall be used to document all changes, no matter how minor, that may affect an instrument, and to identify symptoms that may require future maintenance.

The Center reserves the right to evaluate instrument maintenance records based on QC performance, chromatography, or raw instrument data.

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10.6 Maintenance Hints

Instruments are best maintained when only one operator is responsible for running an instrument and data quality produced. The operator should:

- Understand the strengths and limitations of the instrumentation
- Know how to demonstrate the instrumentation is working well
- Document when the instrument is outside QC limits
- Establish a preventative maintenance schedule to replace consumable parts
- Maintain a supply of critical spare parts
- Identify critical instruments and place them under service contracts.

Multiple operators make operating an instrument more difficult. There is more opportunity for changes that affect the instrument to be overlooked or not communicated to all operators. This requires a higher level of vigilance by all operators to identify, communicate, document, and fix problems as they occur.

10.7 Troubleshooting Hints

When troubleshooting an instrument, consider all the symptoms it is displaying and their possible causes. Change only one variable at a time, and document as you go. When the symptoms disappear, you will know the exact cause, and future occurrences can be quickly fixed.

Subject Chromatography

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Section 11

Chromatography

11.1 Purpose

Center researchers generate many of their critical data using chromatography, both HPLC and GC. A thorough understanding of chromatography is required to ensure these critical instruments are working well.

11.2 Scope

This section describes items that affect accurate chromatographic quantitation and how to ensure data quality.

11.3 Calibration

The chromatograph must be calibrated using a validated standard set prior to use. The calibration curve needs to be checked for linearity, by visual inspection, and accuracy, using a calibration verification standard (CVS). The calibration frequency for an instrument needs to be determined, and the instrument calibrated frequently enough to ensure high-quality data. For the types of chromatographs used in the Center, a good rule of thumb is to recalibrate the instrument every 12 hours and run CVSs periodically between standard sets.

Analytical standards must be prepared from the highest purity starting materials available. Standards should initially be prepared gravimetrically then diluted, if necessary. The standard preparation method should be written and available to all who may prepare standards. The new standard set must be validated by comparing to a CVS or a previously validated set.

The standards should span the concentrations expected in the samples. Samples must not be quantitated outside the upper or lower bounds of the standard curve, but concentrated, diluted, or the calibration curve extended (and validated) to accurately quantitate the sample.

11.4 Calibration Verification Standards

A CVS must be prepared independently from the standards. By using a different source of material (lot or manufacturer), different equipment (balances or volumetric flasks), and different concentrations than the standards, the CVS becomes a powerful tool to check standard curve accuracy. Analyzing a truly independent CVS is preferable to running a standard as an unknown because it checks the purity of reagents, accuracy of the measuring equipment, and accuracy of the calibration curve used to quantitate samples.

When the CVS integration agrees with its known concentration, this is powerful evidence that the entire chromatographic system is working well. The converse is not true, however. When the CVS does not agree with its known value, it demonstrates that something is wrong with the

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chromatographic system. It does not pinpoint the cause of the malfunction, and troubleshooting activities need to begin to isolate the problem. The normal CVS variability for an instrument must be determined. This can be determined by control charting CVSs, and permissible limits can be set. For the types of chromatographs used in the Center, the CVS concentration limits are about 2.5%

11.5 Integration

Integration is the critical step in identifying quantitating peaks in the chromatogram. Peaks are identified by comparing retention times (RTs) to those of known standards. Matching Rts is good evidence (but not solid proof) of a compound's identity. Other compounds may have identical or very similar RTs to the analyte of interest. The RT window used to identify a compound may be quite broad and may match peaks that are clearly misidentified. The normal RT variability of an instrument needs to be determined. For the types of chromatographs used in the Center, RTs should be within 0.02 minutes of a pure standard to be considered a good match.

The peak shape is a critical factor that affects proper quantitation. Co-eluting or tailing peaks can adversely affect quantitation. Careful inspection of the baseline, and the integration starting and ending points are important to accurate quantitation. Manual reintegration may be needed to split poorly resolved peaks so each peak is properly quantitated according to its calibration curve, draw a more sensible baseline, or consistently stop integration on a tailing peak.

11.6 Maintenance

Routine maintenance is critical for the long-term accuracy and operability of the chromatograph. Pure mobile phase such as filtered, degassed solvents for HPLC and high-purity, scrubbed gases for GC prevent many problems that can affect both accuracy and reliability. Consumable parts need to be changed routinely for proper use. Valve rotors, needles, and seats are examples for HPLC, septa, syringes, and injection port liners are examples for GC.

Chromatography operators need to recognize subtle changes that may alert the user of oncoming problems. A confirmation of a leak-free system needs to be done routinely. Changes to operating pressure needs to be identified. A routine check of the absolute area counts for a standard or CVS is very important. Trends in the area counts can alert the user of problems in sensitivity or injection volume. A routine check of the retention times of specific compounds may spot slow shifts. This may identify leaks or restrictions in the flow path.

Subject Documentation of QA/QC Activities

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Section 12

Documentation of QA/QC Activities

12.1 Purpose

Documenting laboratory activities is an important part of an experimental plan. It provides a record demonstrating that QC activities have been consistently applied, and that the data generated have met requirements.

12.2 Scope

This section describes the documentation and archiving activities that support an experimental plan.

12.3 Recording Laboratory Data

Data records shall be handwritten with permanent ink, into a bound laboratory notebook, directly as data are gathered. Technical record books (TRBs) are provided for this use and shall be used according to the instructions given on pages i and ii. TRBs are often assigned to a researcher, but may be assigned to a project with many researchers entering data. When the data are generated using an instrument, all appropriate supporting data shall be entered to a laboratory notebook along with location of raw data.

12.4 Reports

A report shall be written that describes the progress of the plan, experimental results, conclusions drawn, lessons learned, and recommendations for further research. The report shall reference the laboratory notebooks that contain the raw data cited.

12.5 Control Charting

Control charts are powerful tools that demonstrate the long-term stability of a process. Analyses performed for the Center shall have calibration and/or method verification standard results control charted concurrently, as specified in the method. The analytical staff involved in the analysis shall generate control chart information. The results must include the date, analyst's initials, and a laboratory notebook reference. Control records shall be conveniently located for the analyst's use.

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12.6 Analytical Data Archiving

Experimental data gathered by the Center shall be archived so the raw data may be revisited. Paper instrumental printouts shall be affixed to the TRB or a reference to the data location mentioned. Computerized records shall be backed up from the hard disk to a long-term storage medium (tape, optical disk, etc). Instrument printouts shall be stored for 1 year and computerized records for 3 years. Bound laboratory notebooks are kept indefinitely.

12.7 Chain of Custody

The Center distributes items for which receipt must be verified and documented. This may apply to samples, CESs, LAPs, this plan, and other items. When documentation is needed, a chain-of-custody form, which must be signed and returned, shall be sent with these items.

Subject Conformance Evaluation Standards

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Section 13

Conformance Evaluation Standards

13.1 Purpose

The Center uses analytical data gathered from many sources. To be of value, these data must be comparable. The Center has developed conformance evaluation standards (CESs) to test the comparability of various data sources.

13.2 Scope

This section describes the development and use of CESs.

13.3 Conformance Evaluation Standards

CESs are standards developed by the Center for use as blind checks of data generated by various methods or laboratories. They can be purchased from vendors or prepared in-house. The composition of a CES shall be certified by its vendor or ascertained using multiple analyses by approved LAPs. For the CESs to remain blind samples, the composition shall be held as proprietary information within the Center.

13.4 Development of Conformance Evaluation Standards

There are two types of CESs, chemical and biomass standards. Chemical standards are solutions typically used to check an instrument's performance. Biomass standards are feedstock samples the project now uses or plans to use to check the method's performance. Biomass materials chosen for CESs must represent the type of sample being analyzed. They must be homogeneous, stable, of known composition, and in sufficient quantity for long-term usage.

All administrative issues related to CESs as described in this section shall be the responsibility of the quality control coordinator.



Section 14

Quality Assurance for Subcontractors

14.1 Purpose

Subcontractors conduct many research projects for the Center. The analytical data generated must meet the data quality objectives described in the statement of work (SOW) and be comparable to all other Center analyses.

14.2 Scope

This section discusses methods used to ensure subcontractor data meet center goals.

14.3 Subcontractor Methods of Analysis

Subcontractors must follow the analytical methods stated in the SOW. Typically, an SOW requires LAPs to be used. If expressly permitted in an SOW, other analytical methods are allowed, contingent on the subcontractor proving method suitability to the research monitor's (RM) satisfaction.

The Center regards our subcontractors as partners and treats them as valued allies. We recognize that subcontractors have enormous expertise in their areas of research. Recommendations or comments from subcontractor PIs concerning alternate analytical procedures are encouraged and should be addressed to the RM.

14.4 Quality Control Monitoring

For subcontracts that require biomass compositional analysis, the quality control coordinator shall send CESs to new subcontractors. CESs shall also be distributed to subcontractors at the request of the RM, or periodically per the terms of the SOW. Research shall not begin until the CESs have been analyzed to the RM's satisfaction.

The Center reserves the right to monitor specific QC activities under the conditions of the subcontract. If the subcontractor has analytical questions, Center staff members are available for assistance.

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14.5 Approval of Subcontractor CES Results

The RM shall evaluate results of CES analyses submitted by the subcontractors. The subcontractor's results are compared to interlaboratory data and to internally generated databases. The RM shall be responsible for approving CES results and notifying the subcontractor to execute the research plan.

14.6 Subcontractor QA/QC

The subcontractors shall follow all plan provisions and QC details specified in the LAPs. The results of analyses must be presented, with accompanying QC data, in the form specified in the SOW.



Section 15

Glossary

Accuracy: The difference between a measured value and the true value.

Analytical Range: The useful concentration range of an analysis as established by a calibration curve. The linear calibration region above the detection limit and below a maximum concentration where the curve begins to tail.

Bias: An error that consistently, in magnitude and sign, skews a result from the true value.

Blank: An analysis run that uses the same equipment, reagents, and procedure, but without the sample. Used to show the chemicals, glassware, or environment are not producing responses that could be interpreted as having come from the sample.

Calibration: The procedure for establishing or confirming the relationship between precisely known standards and the primary analytical parameter such as absorbance or peak area.

Calibration Verification Standard (CVS): An independent standard that is analyzed to test the accuracy of a calibration curve.

Chain of Custody: A document that records the transfer of responsibility for an item.

Conformance Evaluation Standard (CES): A blind standard developed by the Center to test the comparability of data generated from various laboratories or using various procedures.

Data Quality Objective (DQO): A statement of analytical requirements in an experimental plan.

Detection Limit: The lowest concentration level that can be accurately determined.

Experimental designer: The person responsible to his or her team to conceive, plan, coordinate, and draw conclusions from experiment(s).

Experimental Plan: A written document that describes objectives and methods employed to prove or disprove a hypothesis.

Laboratory Analytical Procedure (LAP): A validated, documented procedure, capable of producing publication-quality data, of general interest to and approved by the Center.

Laboratory Notebook: A bound notebook designed to receive raw scientific data.

Level of Quality: The degree of accuracy, precision, and ruggedness required of the data to support an experimental plan.

Subject Glossary

Section 15

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Matrix: The medium that contains the analytes of interest. The matrix can have a profound effect on a method's ability to quantitate analytes of interest.

Method Validation : The act of documenting the capabilities of a method.

Method Verification Standard (MVS): Materials or spikes used to test the method variability.

Precision: An error that randomly, in magnitude and sign, skews data from the true value.

Quality Assurance (QA): A management system whose purpose is to assure producers and users of analytical services that QC practices are being applied and that the data meet users' requirements.

Quality Control (QC): Actions taken by researchers every day to ensure that the methods and procedures are producing data that meet required specifications.

Quality Control Coordinator: The Center individual responsible for the QA/QC program.

Research Monitor (RM): The NREL person responsible for writing the statement of work, monitoring progress, and defending the conclusions of a subcontractor's work.

Sampling and Analysis Plan (SAP): The part of an experimental plan that describes how samples will be collected and analyzed to meet the plan objectives.

Screening Method: A semiquantitative method used for tracking or quick process feedback; it is not capable of highly accurate or precise results.

Standard: Material with accurately and precisely known characteristics used to calibrate analytical instruments.

Statement of Work (SOW): A contractual agreement between NREL and subcontractors to perform research or services.

Subcontractor: An outside group that performs research or services for NREL per an SOW.

Subcontractor Principal Investigator (PI): The leader of a group conducting subcontract research for NREL responsible for research quality and for completing the terms of the subcontract.

True Value: A hypothetical value known with no bias or precision errors.

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Abstract (If paper has abstract already on it, just say “see paper”).

This plan is designed to ensure that all experimental data meets Center needs. The plan describes the Center's experimental measurement goals, quality assurance responsibilities, and a set of tools that can be used to meet these goals. The central concept of the plan is that quality data is everyone's responsibility.

Keywords (5-7)

QAP, Quality, Experimental plan